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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
24-27 May 2006

Initial marketing authorisation applications
The Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions on initial marketing authorisation applications for:

- **Competact** (pioglitazone/metformin), from Takeda Global R & D Centre (Europe) Ltd, for the treatment of type II diabetes. EMEA review began on 14 March 2005 with an active review time of 204 days.
- **Intrinsa** (testosterone) and **Livensa** (testosterone), from Procter and Gamble Pharmaceuticals UK, for the treatment of hypoactive sexual desire disorder in women who have uterus and both ovaries removed. EMEA review for both products began on 15 November 2004 with an active review time of 210 days.
- **Savene** (dexrazoxane), from TopoTarget A/S, for the treatment of anthracycline extravasation (accidental leakage of intravenously administered chemotherapeutics into the surrounding tissue). EMEA review began on 17 August 2005 with an active review time of 204 days. Savene is the twenty-eighth orphan medicinal product to receive a positive CHMP opinion.
- **Thelin** (sitaxentan sodium), from Encysive (UK) Ltd, for the treatment of pulmonary arterial hypertension. EMEA review began on 17 August 2005 with an active review time of 196 days. Sitaxentan sodium is the twenty-ninth orphan medicinal product to receive a positive CHMP opinion.

Re-examination procedure
The Committee for Medicinal Products for Human Use (CHMP) has adopted a final positive opinion for **ATryn**, from Genzyme Europe. ATryn, which contains antithrombin alfa, a recombinant-DNA human anti-clotting blood protein, is the first medicinal product derived from transgenic biotechnology to receive a positive opinion from the Committee. Antithrombin alfa is extracted from the milk of goats which have the human antithrombin gene inserted, that enables them to produce the human protein in their milk.
Following re-examination of its negative opinion, adopted in February 2006, the CHMP has now adopted a final positive opinion, recommending that ATryn should be authorised for use in patients with congenital antithrombin deficiency (inherited reduction of antithrombin) undergoing surgery, to prevent deep-vein thrombosis (formation of clots in the vessels of the legs) and thromboembolism (formation of clots in other vessels of the body).

A separate press release and question and answer document are available.

Extensions of indications
The Committee adopted positive opinions on the extension of indication of medicinal products that are already authorised in the European Union:

- Mabthera (rituximab), from Roche Registration Ltd, to extend its indications to add:
  - maintenance therapy indicated for patients with relapsed/refractory follicular lymphoma responding to induction therapy with chemotherapy with or without Mabthera.
  - use in combination with methotrexate for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-

modifying anti-rheumatic drugs including one or more tumour necrosis factor (TNF) inhibitor therapies.

Mabthera was first authorised in the European Union on 2 June 1998 and is currently indicated for treatment of follicular lymphoma.

- **Remicade** (infliximab), from Centocor B.V., to extend its indication to include use of infliximab alone or in combination with methotrexate in the treatment of psoriatic arthritis patients. Remicade was first authorised in the European Union on 13 August 1999 and is currently approved for the treatment of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, psoriasis and ulcerative colitis.

Summaries of opinions for all these products are available and can be found here.

Review procedures concluded

The Committee concluded an arbitration procedure for the generic product **Ceftriaxone Tyrol 1g and 2g** (ceftriaxone) from Sandoz Ltd, recommending harmonisation of the product information of the reference product and of the generic product, in particular concerning the dosing of newborn infants. The procedure was initiated by the United Kingdom under Article 29(2) of Directive 2001/83/EC as amended.

Finalising a harmonisation referral for **Neurontin** (gabapentin) and associated names, from Pfizer, the Committee recommended harmonisation of the summaries of product characteristics across the European Union, in particular with regard to indications, posology, contra-indications and undesirable effects. The referral was initiated by Italy under Article 30 of Directive 2001/83/EC as amended.

Concluding referral procedures under Article 36 of Directive 2001/83/EC as amended, for a number of generic medicines containing **cetirizine dihydrochloride 10 mg** (film coated tablets), the Committee recommended their suspension because of concerns regarding good clinical practices (GCP) and good laboratory practices (GLP) compliance that impact on the quality and reliability of bioequivalence studies supporting the marketing authorisations.

Review procedures started

The Committee started a large number of arbitration and referral procedures for medicinal products authorised through the mutual recognition procedure this month.

Arbitrations under Article 29 of the Community code on human medicinal products (Directive 83/2001/EC as amended) are initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure. Procedures were started for the following products:

- **Felodipine/metoprolol tartrate** and associated names (felodipine metoprolol tartrate), from Yes Pharmaceuticals Development Services GmbH
- **Ciprofloxacin 2mg/ml solution for infusion** (ciprofloxacin), from Nycomed Danmark APS.

A harmonisation referral under Article 30 of the Community code on human medicinal products (Directive 83/2001/EC as amended) was started for **Lornoxicam** (lornoxicam) at the request of the marketing authorisation holder, Nycomed. Article 30 referrals are initiated with a view to harmonising product information for medicinal products authorised at Member State level.

Referral procedures under Article 36 of the Community code on human medicinal products (Directive 83/2001/EC as amended) were begun for **Gadovist** and **Gadograf**, from Schering España. Article 36 procedures are initiated where a Member State considers that there are public health issues relating to a product that may require regulatory action. The referrals were made by Spain with a view to restricting the indication of the products.

A more detailed CHMP meeting report will be published shortly.

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